

Application No.: 10/691,849
Amendment and Response dated November 20, 2006
Reply to Office Action of August 23, 2006
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Amendments to the Drawings:

[None being submitted].

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Remarks/Arguments:

Introduction

The specification has been amended to correct minor typographical errors and to update the status of certain applications cited therein. No new matter is introduced with these amendments. Entry of these amendments is respectfully requested.

Claims 31-65 are pending. Claims 1-30 have been canceled. Claims 34, 39, 47 and 55 are withdrawn. Claim 31, 37, 42, 45 and 52 have been non-narrowingly amended to correct minor typographical errors and to correct antecedent basis. Claims 56-65 have been added. Support for added claim 56 may be found in originally filed claims 31, 37, 39 and 41. Support for added claims 57-65 may be found in originally filed claims 57, 58, 35, 36, 38, 40, 41, 43 and 44, respectively. No new matter has been introduced with these claim amendments. Entry of the claim amendments is respectfully requested.

Section 103 Rejections

Claims 31-33, 35, 36, 40-46 and 50-54 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent Application Publication No. 2001/0029349 to Leschinsky (hereinafter "Leschinsky") in view of U.S. Patent No. 3,653,959 to Kehr et al. (hereinafter "Kehr") and further in view of U.S. Patent No. 6,495,127 to Wallace et al. (hereinafter "Wallace"). Applicants respectfully traverse.

Leschinsky discloses that a solution of glutaraldehyde, or carbodiimide may be used to strengthen an aneurysmal wall by crosslinking with the collagen within the wall, as follows:

The purpose of the chemical solution is to strengthen aneurysmal wall 23 by actually changing the nature of the wall 23, i.e. crosslinking the collagen in the wall 23. ... [T]he preferred solutions are aldehydes and especially glutaraldehyde.... Another possible crosslinking agent is

carbodiimide.... (Leschinsky, paragraphs [0042] - [0043])
(emphasis added)

Thus, Leschinsky teaches a specific solution, i.e., a solution of glutaraldehyde, or carbodiimide, may be introduced into a bodily lumen to interact with the collagen within an aneurismal wall. Leschinsky, however, fails to teach or suggest that its chemical solution of glutaraldehyde or carbodiimide is in itself a curable embolic material. Indeed, Leschinsky specifically describes that its chemical solutions are to interact with a vessel wall, but are not curable by themselves as they are to be removed from the bodily lumen, as follows:

[A] chemical solution, preferably glutaraldehyde, other examples of which were described and listed in reference to first and second embodiments, is pumped through tube 150, infusion/vacuum lumen 132 and port 152 into treatment chamber 41. As indicated above the chemical solution actually changes the nature of wall 22. Next, the chemical solution is pumped out of port 152, through infusion/vacuum lumen 132, and out tube 150. The flushing and chemical solution infusion cycles may be repeated as necessary. ... Following treatment with the chemical solution another flushing solution may be employed to remove excess chemical solution from treatment chamber 41. (Leschinsky, paragraph [0050], lines 10-26) (emphasis added)

Thus, Leschinsky describes a chemical solution which crosslinks with collagen, but is not by itself a curable solution.

In contrast to Leschinsky's non-curable solution of solution of glutaraldehyde or carbodiimide for interacting with collagen in a vessel lumen, Kehr is directed toward compositions for encapsulating electronic and microelectronic components. The examiner specifically directs the Applicants to Example 12 at column 11 of Kehr. In that example, pentaerythritol tetrakis (β -mercaptopropionate) was combined with the Prepolymer D from Example 4 and cured under conditions of Example 9. (Kehr, column 11, lines 11-17). The

Prepolymer D of Example 4, however, is specifically based upon polyethylene glycol and not polyethylene glycol diacrylate, as set forth in the claims of the subject application. (See. e.g., Kehr, column 9, line 42). Further, Kehr's composition of Example 12 was cured by exposure a 275 watt Sylvania RS sun lamp at a surface intensity of 4,000 microwatts/cm² for 5 minutes. (Kehr, column 10, lines 61-63). It is respectfully submitted that such a cure is not an *in situ* cure within a bodily lumen as proposed by the Office Action at page 3, lines 7-8.

The broader aspects of Kehr offer little additional support for a *prima facie* case of obviousness. Kehr does refer to a composition having polyene and polythiol, where the polyene may include a polyethyleneether glycol diacrylate having a molecular weight of about 750 (Kehr, column 3, lines 56-57) and where the polythiol may include a pentaerythritol tetrakis (β -mercaptopropionate) (Kehr, column 5, line 55). The composition is preferably cured by exposure to electromagnetic radiation. (Kehr, column 7, lines 12-13). Such a curing mechanism, however, is contrary to the *in situ* curing proposed by the examiner. Alternatively, a free radical generator, such as a peroxide, may be used to cure the compositions of Kehr within a mold. (Kehr, column 8, lines 41-45). One of ordinary skill in the art would not be motivated to replace the peroxide of Kehr with biological buffers, such as 2-[(2-aminoacetyl)amino]acetic acid (glycylglycine) and/or N-[2-hydroxyethyl]piperazine-N'-[2-ethanesulfonic acid] (HEPES), to effect the curing if its compositions because Kehr is silent as to the use of biological buffers.

Wallace describes the use of polyethylene glycol (and not polyethylene glycol diacrylate) at column 6, line 65, and pentaerythritol tetrakis (3-mercapto-propionate) at column 7, lines 58-59, as different compositions for use as surgical sealing purposes. Wallace, however, states that pentaerythritol tetrakis (3-mercapto-propionate) should not be used in polyalkylene oxide based systems. (Wallace, column 7, lines 54-61). Thus, even assuming *arguendo* that one of ordinary skill in the art would substitute polyethylene glycol diacrylate with the polyethylene glycol of Wallace, Wallace teaches that pentaerythritol tetrakis (3-

mercapto-propionate) should not be combined with polyalkylene oxide based compositions. Moreover, Wallace teaches that pH may be adjusted for controlling the gelling of amino-PEG and sulfhydryl-PEG compositions. (Wallace, column 12, lines 28-35). Wallace fails to teach that a buffer may be used to effect the curing of polyethylene glycol diacrylate and pentaerythritol tetra 3(mercaptopropionate) compositions.

Thus, it is respectfully submitted that claims 31-33, 35, 36, 40-46 and 50-54 are patentably distinct over Leschinsky, Kehr and Wallace, individually or in combination. Reconsideration and withdrawal of the rejection submitted that claims 31-33, 35, 36, 40-46 and 50-54 are respectfully requested.

Moreover, it is respectfully submitted that Leschinsky, Kehr and Wallace, individually or in combination, fail to teach or suggest the specific proportions of pentaerythritol tetra 3(mercaptopropionate) and polyethylene glycol diacrylate present and the use of a specific buffer, such as glycylglycine, as set forth in independent claim 56. Thus, it is also respectfully submitted that claims 56-55 are patentably distinct over Leschinsky, Kehr and Wallace, individually or in combination.

Claims 37, 38, 48 and 49 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Leschinsky in view of Kehr and Wallace, and further in view of U.S. Patent No. 5,646,007 to Enomoto et al. (hereinafter "Enomoto"). Applicants respectfully traverse.

Enomoto merely teaches that HEPES or glycylglycine may be used as buffers to control the pH of a thrombin reagent and a chromogenic substrate reagent. (Enomoto, column 5, lines 40-44). It is respectfully submitted that the control of pH of solutions of thrombin and chromogenic substrate reagents would not provide motivation to one of ordinary skill in the art to modify the teachings of Leschinsky, Kehr, and/or Wallace, individually or in combination, to arrive at, *inter alia*, the specifically defined curable embolic materials of the present invention. Thus, it is respectfully submitted that claims 37, 38, 48 and 49 are patentably distinct over

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Leschinsky, Kehr, Wallace and Enomoto, individually or in combination. Reconsideration and withdrawal of the rejection submitted that claims 37, 38, 48 and 49 are respectfully requested.

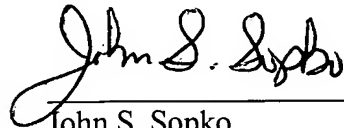
Summary

Therefore, Applicants respectfully submit that independent claims 31, 45 and 56, and all claims dependent therefrom, are patentably distinct. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R. § 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

Respectfully submitted,



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